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The effectiveness of mineral trioxide aggregate, calcium hydroxide and formocresol for pulpotomies in primary teeth

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Abstract

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Aim To compare the effectiveness of mineral trioxide aggregate (MTA), calcium hydroxide (CH) and formocresol (FC) as pulp dressing agents in carious primary teeth.

Methodology Forty-five primary mandibular molars with dental caries in 23 children [AUTHOR QUERY: How many children?] between 5 and 9 years old were treated by a conventional pulpotomy technique. The teeth were randomly assigned to the experimental (CH or MTA) or control (FC) groups. After coronal pulp removal and haemostasis, remaining pulp tissue was covered with MTA paste or CH powder in the experimental groups. In the control group, diluted FC was placed with a cotton pellet over the pulp tissue for 5 min and removed; the pulp tissue was then covered with zinc oxide–eugenol (ZOE) paste. All teeth were restored with reinforced ZOE base and resin modified glass–ionomer cement. Clinical and radiographic successes and failures were recorded at 3, 6, 12, 18 and 24 month follow-up.

Results Forty-three teeth were available for follow-up. In the FC and MTA groups, 100% of the available teeth were clinically and radiographically successful at all follow-up appointments; dentine bridge formation could be detected in 29% of the teeth treated with MTA. In the CH group, 64% of the teeth presented clinical and radiographic failures detected throughout the follow-up period, and internal resorption was a frequent radiographic finding.

Conclusions Mineral trioxide aggregate was superior to CH and equally as effective as FC as a pulpotomy dressing in primary mandibular molars. Internal resorption was the most common radiographic finding up to 24 month after pulpotomies performed with CH.

Keywords: calcium hydroxide, children, deciduous tooth, formocresol, mineral trioxide aggregate, pulpotomy, success and failure rate.

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Introduction

When the carious process exposes the pulp, the tissue close to the lesion becomes inflamed (Eidelman *et al.* 2001). Pulpotomy is a common therapy for cariously exposed pulps in symptom-free primary molar teeth (Eidelman *et al.* 2001, Fuks 2002, Agamy *et al.* 2004, Jabbarifar *et al.* 2004, Huth *et al.* 2005, Maroto *et al.* 2005), and its aims are to retain a functional tooth in the oral cavity until its exfoliation through the preservation of the radicular pulp (Fuks 2002, Huth *et al.* 2005, Maroto *et al.* 2005, Saltzman *et al.* 2005).

Formocresol (FC) has been a popular pulpotomy medicament in the primary dentition for the past 60 years. It produces an area of necrosis in the pulp

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adjacent to the wound (Cengiz *et al.* 2005, Waterhouse *et al.* 2000b, Salako *et al.* 2003, Agamy *et al.* 2004). Most often the pulp tissue is altered by the formaldehyde and appears 'fixed' *in situ* and therefore does not undergo immediate liquifactive necrosis in the root canal (Torneck 1972, Peng *et al.* 2006). FC is considered as the gold standard dressing agent for pulpotomy therapy, but concerns about its safety have arisen recently (Ranly 1994, Eidelman *et al.* 2001, International Agency for Research on Cancer, World Health Organization 2004, Huth *et al.* 2005, Naik & Hegde 2005, Kaaren *et al.* 2006, Tunç *et al.* 2006).

With the introduction of calcium hydroxide (CH), a new era in vital pulp therapy began. Clinical success rates ranging from 31 to 100% have been reported for CH as a pulpotomy dressing (Magnusson 1970, Schröder 1978, Waterhouse 1995, Waterhouse *et al.* 2000a, Percinoto *et al.* 2006). The alkaline pH induced by CH not only neutralizes lactic acid from osteoclasts, thus preventing dissolution of the mineral components of dentine, but can also activate alkaline phosphatases, which play an important role in hard tissue formation (Mitchell & Shankwalker 1958, Tronstad *et al.* 1981). Although systemic and local toxicity are absent, adequate control of bleeding is difficult to achieve in order to allow for a good contact between the medicament and the pulp tissue (Schröder 1978, Heilig *et al.* 1984, Waterhouse *et al.* 2000a, Tunç *et al.* 2006). Moreover, there are controversies regarding its application in primary teeth pulpotomies because of the possibility of internal resorption (Schröder 1978, Waterhouse 1995, Waterhouse *et al.* 2000b).

Recently, with the development of materials that are not only biocompatible but also bio-inductive, the emphasis has shifted from mere preservation to regeneration of the remaining pulp tissue. One such material, which has shown immense potential for regeneration, is mineral trioxide aggregate (MTA) (Chacko & Kukirose 2006). MTA was developed with the purpose of serving as an apical root-end filling material, but it has also proven to be successful in vital pulp therapy procedures both in animals (Faraco & Holland 2001, Menezes *et al.* 2004) and humans (Eidelman *et al.* 2001, Barrieshi-Nusair & Qudeimat 2006, Sari & Sönmez 2006, Aeinehchi *et al.* 2007, Moretti *et al.* 2007). MTA is a biocompatible material and its sealing ability is better than that of amalgam or zinc oxide–eugenol (Torabinejad & Chivian 1999, Eidelman *et al.* 2001, Chacko & Kukirose 2006). Furthermore, its ability to stimulate cytokine release from bone cells has been demonstrated, indicating that it actively promotes hard tissue formation (Koh *et al.* 1995, Eidelman *et al.* 2001).

The purpose of this study was to evaluate and compare, both clinically and radiographically, the effects of MTA, CH and FC as pulp dressings after coronal pulp amputation in decayed primary molars.

Material and methods

Participants

The Ethics Committee of Bauru School of Dentistry, University of São Paulo approved the protocol of this study. During the pre-treatment screening period, the parents or guardians of the children received detailed information concerning the nature and the procedures involved in the study and signed informed consent forms.

The criteria for selection of the teeth to be included in the study were: children between the ages of 5 and 9 years old, with no more than two decayed mandibular primary molar teeth with vital pulp and absence of history of pain, thus requiring a pulpotomy therapy; no clinical or radiographic evidence of pulp degeneration, such as excessive bleeding from the root canal, internal root resorption, inter-radicular and/or furcal bone destruction; no physiological root resorption of more than one-third, as observed in periapical radiographies; and the possibility of proper restoration of the teeth. Exclusion criteria included the presence of systemic pathology and any history of allergic reaction to latex, local anaesthetics or to the constituents of the test pulp dressing agents.

Technique

The suitability of the teeth for pulpotomy was assessed by three of the authors, who also performed the procedures. The authors were previously involved in several pulpotomy studies and used a standardized technique.

The primary mandibular molars were assigned by a random number producing system to either the experimental groups (CH or MTA) or to the control group (FC). In case a child had two molars needing pulpotomy, the second tooth was randomly assigned to one of the other groups. In all groups, after local anaesthesia with 2% mepivacaine with 1 : 100 000 epinephrine and rubber dam isolation, caries removal was accomplished with handpiece with a round bur. The opening of the pulp chambers was conducted with round

carbide bur. Coronal pulp tissue was removed manually with an excavator. The wound surface was continuously irrigated with saline solution until bleeding ceased (Granath & Hagman 1971).

In the control group, a cotton pellet moistened with diluted FC (1 : 5 Buckley's solution – Biodinâmica Química e Farmacêutica Ltda., Ibiporã, PR, Brazil) was placed on the amputated pulp and removed after 5 min. The remaining pulp tissue was covered with zinc oxide–eugenol paste (ZOE). In the CH group, the pulp tissue was dressed with calcium hydroxide P.A. (Biodinâmica Química e Farmacêutica Ltda., Ibiporã, PR, Brazil) slightly dampened. Care was taken to create a complete seal of the pulp tissue with CH, whilst avoiding excess of the material. For the MTA group, a paste obtained by mixing gray MTA powder (Ângelus, Londrina, PR, Brazil) with sterile saline at 1 : 1 powder/saline ratio was placed into the pulp chamber. In all of the groups, a layer of reinforced ZOE (IRM®; Dentsply, Petrópolis, PR, Brazil) was placed prior to restoration with glass–ionomer cement (Vitremer®; 3M ESPE, São Paulo, SP, Brazil) (Fuks 2002, Holan *et al.* 2005). Immediate postoperative periapical radiographies were taken in order to assure that the dressing agents were correctly placed over the remaining radicular pulp and to serve as the initial parameter for further postoperative evaluations.

Follow-up

At follow-up appointments, clinical success was confirmed in teeth presenting with no spontaneous pain, mobility, swelling, fistula and smell. Radiographic success was considered if internal root resorption, inter-radicular bone destruction and furcation radiolucency were absent. Dentine bridge formation was also considered a radiographic success; intracanal calcifications were not considered as failures.

Periodic follow-up examinations were carried out 3, 6, 12, 18 and 24 months after the end of the treatment. Each checkup involved a clinical and periapical radiographic examination of the pulpotomized teeth, which was performed by two blinded and previously calibrated investigators (kappa values of 0.83 and 0.96 for inter- and intra-examiner reproducibility, respectively). When disagreement arose, a consensus approach was adopted.

Data were submitted to statistical analysis using the chi-squared test followed by a multiple comparison post-test. Statistical significance was established at 5%.

Results

A total of 45 primary molars in 23 children (nine females and 14 males, with mean age of 6 years and 5 months) were randomly allocated to the three treatment groups (15 teeth per group). Of these, 43 teeth were available for follow-up evaluation after 3, 6, 12, 18 and 24 months. Two children with one tooth each in CH and MTA groups were lost to follow-up because they moved to another city.

In the FC and MTA groups, 100% of the available teeth were clinically and radiographically successful during all the follow-up appointments. No teeth showed signs of mobility, fistula, swelling or inflammation of the surrounding gingival tissue. Four of 15 teeth in the FC group and five of 14 teeth in the MTA group exfoliated throughout the follow-up period (Fig. 1).

In the CH group, internal resorption was detected radiographically in five teeth (35.7%) at the 3-month follow-up. After 6 months, six teeth (42.9%) had radiographic evidence of failure including internal resorption, inter-radicular bone destruction and furcation radiolucency. Of these, two molars were also clinical failures because of the presence of mobility, swelling and fistula, and were then extracted. After 12 months, four radiographic failures and four clinical failures were observed (two teeth presented both failures). The teeth presenting clinical failures were extracted. At 18- and 24-month follow-up appointments, two teeth remained presenting radiographic failures. Additionally, the exfoliation of one tooth was detected after 18 months (Fig. 1).

Regarding internal resorption, a statistically significant difference could be observed when comparing CH with the two other groups at all follow-up appointments (Table 1, $P < 0.05$). Tables 2, 3 and 4 show the failures concerning inter-radicular bone destruction, tooth mobility and fistula, respectively, detected clinically and radiographically when the teeth were treated with FC, CH and MTA. No dentine bridge was detected in the FC group throughout the follow-up period. However, after 6 months of the end of treatment performed with CH and MTA, dentine bridge formation could be observed, and statistically significant differences regarding this parameter were found between FC and CH and between FC and MTA at 12-, 18- and 24-month follow-up appointments (Table 5, $P < 0.05$).

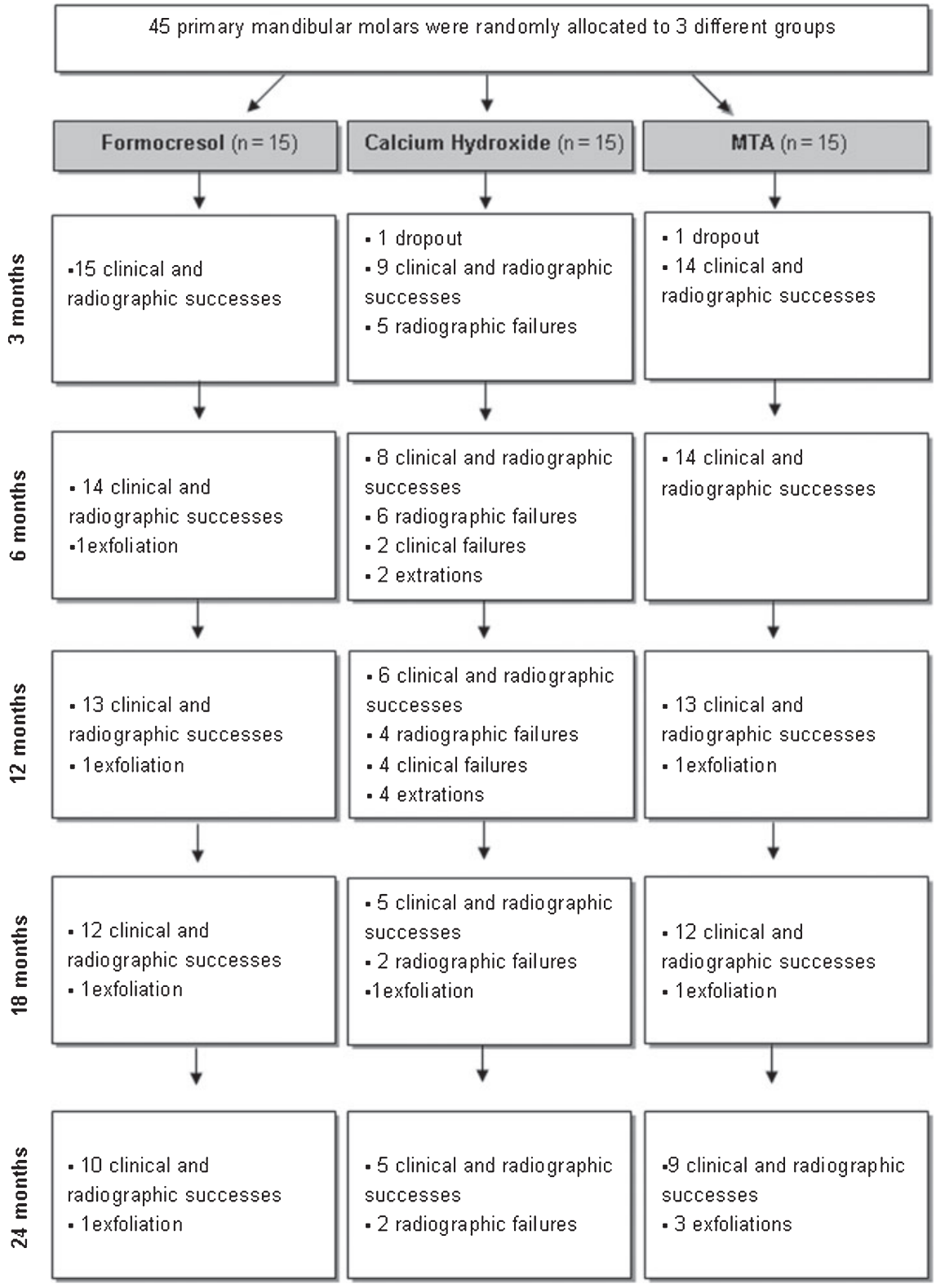

Figure 1 Flow of patients and pulpotomized teeth up to 24 months.

Table 1 Internal resorption observed radiographically for formocresol, calcium hydroxide and MTA pulpotomies at 3-, 6-, 12-, 18- and 24-month follow-up

Groups	3 months	6 months	12 months	18 months	24 months
FC	0	0	0	0	0
CH	5[a]	6[a]	6[a]	6[a]	6[a]
MTA	0	0	0	0	0

[a]Statistically significant difference ($P < 0.05$).

Table 2 Inter-radicular bone destruction observed radiographically for formocresol, calcium hydroxide and MTA pulpotomies at 3-, 6-, 12-, 18- and 24-month follow-up

Groups	3 months	6 months	12 months	18 months	24 months
FC	0	0	0	0	0
CH	0	3	4[a]	4[a]	4[a]
MTA	0	0	0	0	0

[a]Statistically significant difference ($P < 0.05$).

Table 3 Tooth mobility detected clinically for formocresol, calcium hydroxide and MTA pulpotomies at 3-, 6-, 12-, 18- and 24-month follow-up

Groups	3 months	6 months	12 months	18 months	24 months
FC	0	0	0	0	0
CH	0	2	4[a]	4[a]	4[a]
MTA	0	0	0	0	0

[a]Statistically significant difference ($P < 0.05$).

Table 4 Fistula detected clinically for formocresol, calcium hydroxide and MTA pulpotomies at 3-, 6-, 12-, 18- and 24-month follow-up

Groups	3 months	6 months	12 months	18 months	24 months
FC	0	0	0	0	0
CH	0	2	4[a]	4[a]	4[a]
MTA	0	0	0	0	0

[a]Statistically significant difference ($P < 0.05$).

Table 5 Dentin bridge formation observed radiographically for formocresol, calcium hydroxide and MTA pulpotomies at 3-, 6-, 12-, 18- and 24-month follow-up

Groups	3 months	6 months	12 months	18 months	24 months
FC	0	0	0	0	0
CH	3	8[a]	7[a]	7[a]	7[a]
MTA	0	1	4[a]	4[a]	4[a]

[a]Statistically significant difference ($P < 0.05$).

Discussion

This study assessed the clinical and radiographic success and failure rates of pulpotomies performed in primary molar teeth with three different dressing agents. CH and FC are commonly used for primary teeth pulpotomy procedures, whereas MTA is a relatively new material currently being investigated as potential agent for pulp therapies in both primary and permanent dentitions (Salako *et al.* 2003). Taking into account that FC is still considered the gold standard in primary tooth pulpotomy, it was selected as the control group. However, as a result of its reported toxic, mutagenic and carcinogenic properties (Waterhouse 1995, Eidelman *et al.* 2001, International Agency for Research on Cancer, World Health Organization 2004, Kaaren *et al.* 2006, Percinoto *et al.* 2006), it seems obvious that many specialists in paediatric dentistry would replace FC if they were able to identify an effective and nontoxic alternative material (Farsi *et al.* 2005). It is worth mentioning that ferric sulphate has been proposed as a substitute for FC, which some would consider the new gold standard for pulpotomies (Fuks 2002, Huth *et al.* 2005, Patchett *et al.* 2006, Srinivasan *et al.* 2006).

Until the studies carried out with MTA (Aeinehchi *et al.* 2002, 2007, Agamy *et al.* 2004, Jabbarifar *et al.* 2004, Farsi *et al.* 2005, Maroto *et al.* 2005, Naik & Hegde 2005), none of the products proposed as alternatives to FC had shown greater efficacy or better clinical outcomes for pulpotomy treatment in primary teeth (Elliot *et al.* 1999, Waterhouse *et al.* 2000a, El Meligy *et al.* 2001, Saltzman *et al.* 2005). Although the results reported here with the use of FC demonstrated high clinical and radiographic success rates, several histological reports have described the presence of a chronic inflammatory process (Cengiz *et al.* 2005 , Torneck 1972, Waterhouse *et al.* 2000a,b, Salako *et al.* 2003, Percinoto *et al.* 2006). In the present study, FC and MTA had similar efficacy and both had better outcomes than CH. These results corroborate the findings of other reports, which demonstrated the superiority of MTA in comparison with CH (Aeinehchi *et al.* 2002, Chacko & Kukirose 2006.

Some authors do not consider internal resorption as a sign of failure (Smith *et al.* 2000, Holan *et al.* 2005, Maroto *et al.* 2005). However, the aetiology of internal resorption is thought to be the result of chronic pulpitis (Law 1956, Foreman & Barnes 1990, Waterhouse *et al.* 2000b), and in order for internal resorption to become progressive, there must be necrotic tissue

present (Tronstad 1988). Therefore, pulpotomy cannot be regarded as successful if it presents any pathologic consequence of the treatment, even if the permanent successor erupts into its proper location whithout enamel defects (Eidelman *et al.* 2001). In the present study, although internal resorption was categorized as a radiographic failure, the teeth presenting this pathology were not treated immediately, but left for follow-up observation. This approach was adopted because the teeth were asymptomatic and did not show any sign of clinical failure. In addition, not every pathological finding in a primary tooth requires intervention because primary tooth survival or the permanent successor may not necessarily be affected. However, in most of the cases, internal resorption in CH-treated teeth progressed continually, and involved osseous changes, and clinical signs and symptoms could be detected in further follow-up appointments. Therefore, extraction of the affected teeth was necessary. Furthermore, it is reasonable to mention that irrespective of the material employed, a periodical clinical and radiographic evaluation of teeth submitted to pulp treatment must be emphasized.

Bleeding control after coronal pulp amputation is considered a significant variable in the results of pulpotomies with CH (Schröder 1973, 1978, Heilig *et al.* 1984, Tunç *et al.* 2006). Advocates for the use of CH suggest that the sequel of internal resorption can be prevented by the direct contact of CH with sectioned pulp tissue (Schröder 1973). Although this can be technically difficult to achieve and is biologically suspect because an incision into vital tissue produces both haemorrhage and exudation (Waterhouse *et al.* 2000b), care was taken in order to avoid leaving a blood clot between the remaining pulp and CH. The same approach of bleeding control was employed in the other two groups. However, the fact that MTA hardens in the presence of moisture should be emphasized, which may have evoked a better sealing of pulp chamber, and consequently better results, as compared with CH. Therefore, MTA can be used in areas in which it is virtually impossible to achieve a totally dry environment, as for example in pulp chambers (Maroto *et al.* 2005).

Dentine bridge formation could be detected in CH- and MTA-treated teeth, which supports the suggestion that both materials have a similar mechanism of action with regard to bridging (Holland *et al.* 1999, 2001, Dominguez *et al.* 2003, Chacko & Kukirose 2006, Percinoto *et al.* 2006). Although MTA does not have calcium hydroxide in its composition, it has calcium oxide that could react with tissue fluids to form calcium hydroxide (Holland *et al.* 1999). However, a more rapid process of bridge formation with the use of CH is suggested in the present work because a greater number of dentine bridges could be radiographically detected in the CH group as compared with the MTA group at 3- and 6-month follow-up appointments (Table 5, $P < 0.05$). Hence, this result disagrees with the speculation that the mineralization process is slowed down by the minute element weight percentage of magnesium, because MTA has lower values of magnesium than CH (Dominguez *et al.* 2003, Chacko & Kukirose 2006).

The concept of dentine bridging is controversial because the presence of a bridge can be viewed as either a healing response or a pulp reaction to irritation (Dominguez *et al.* 2003, Chacko & Kukirose 2006). Waterhouse *et al.* (2000b) suggested that reactionary dentine formation is a sign or consequence of attempted repair processes within the pulp tissue. Nevertheless, after an initial attempt by the pulp tissue to 'wall-off' the insult, the protective or reactive process may fail, leading to clinical failure. In this study, none of the teeth with dentine bridge had other concomitant radiographic or clinical signs of failure (data not shown), and therefore its presence was categorized as a radiographic success. However, it is worth mentioning that histological analysis would be an important approach to assess the pulp tissue condition of all pulpotomized teeth, which would allow the nature and quality of the dentine bridges to be examined. Thus, the histological failure and success rates could also be determined. Furthermore, the formation of a bridge does not imply that the pulp will be sealed completely from the environment (Schuurs *et al.* 2000, Chacko & Kukirose 2006). Cox *et al.* (1996), in a study in primates, observed that 89% of all dentine bridges formed following capping procedures with CH had tunnel defects, and 41% of the dentine bridges were associated with recurring pulp inflammation.

Healing of the dental pulp is not exclusively dependent on the supposed stimulatory effect of a particular type of medicament but is directly related to the capacity of both the dressing and definitive restorative material to provide a biological seal against immediate and long-term microleakage along the entire restoration interface (Jabbarifar *et al.* 2004, Chacko & Kukirose 2006, Percinoto *et al.* 2006). One such material that provides optimal coronal seal is a stainless steel crown (Eidelman *et al.* 2001, Agamy *et al.* 2004, Jabbarifar *et al.* 2004, Farsi *et al.* 2005,

Maroto *et al.* 2005, Naik & Hegde 2005). However, in this study, all pulpotomized teeth were restored with resin-modified glass–ionomer cement (RMGIC), which has good sealing properties, is easy to handle (Hewlett & Mount 2003), and its adhesive properties impart adequate retention even if mechanical undercuts are absent. Coverage of exposed dentine and sharp margins with RMGIC to provide patient comfort is possible with minimal chair time (Hewlett & Mount 2003, Moretti *et al.* 2007). Therefore, the impaction of the restorative material was not a discriminating factor amongst the three groups. Additionally, it is important that the absence of evidence for RMGIC should not be misinterpreted as evidence for its lack of efficacy.

Conclusions

Mineral trioxide aggregate was more successful than CH for pulpotomies in primary molar teeth as none of the MTA-treated teeth showed any clinical or radiographic pathology, whereas internal resorption was a common radiographic finding in teeth treated with CH up to the 24-month follow-up appointment. Although MTA and FC are equally effective, concerns about cytotoxicity and potential mutagenicity of FC still remain. Taken together, the present data support the suggestion that MTA is a suitable replacement for FC in primary molar pulpotomies.

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